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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,335	07/25/2005	Laurent Cavarec	G-194US03PCT	9318

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
11/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,335	CAVAREC ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-56,58-60,62,63 and 87-89* is/are pending in the application.

4a) Of the above claim(s) *53,62,63,88 and 89* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-52,54-56,58-60 and 87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/26/7*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 50, 52, 55-56, 58-60 and 87 have been amended and claims 57 and 61 have been cancelled as requested in the amendment filed on September 26, 2007. Following the amendment, claims 50-56, 58-60, 62, 63 and 87-89 are pending in the instant application.

Claims 53, 62, 63, 88 and 89 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 27, 2007.

Claims 50-52, 54-56, 58-60 and 87 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on September 26, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 50-52, 54-56, 58-60 and 87 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility for reasons of record in section 4 of Paper mailed on May 07, 2007. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological

role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

Applicant traverses the rejection on the premise that, "one skilled in the art would have recognized that homomultimers of the claimed polypeptide would have been useful for the identification of compounds suitable for the treatment of diseases, such as bipolar disease" (p. 5 of the Response). Applicant's argument has been fully considered but is not persuasive for the following reasons.

At pp. 5-6 of the Response, Applicant submits that the instant specification and prior art disclose the following information, which supports the utility of the instant claimed invention:

(1) KCNQ2 forms a functional potassium channel, which is phosphorylated by kinases and binds to PP2A/Bγ;

(2) KCNQ channels can be phosphorylated or dephosphorylated;

(3) activity/phosphorylation state of KCNQ is modulated by lithium;

(4) lithium is a compound known to treat bipolar disorder.

As an initial matter, the Examiner does not doubt or dispute any of the actual findings (data) presented in the instant specification. However, the disclosed results of experiments fail to establish support of the assertion that a compound, "capable of inhibiting phosphorylation of the polypeptide of SEQ ID NO: 2 *in vitro* [is a] candidate compound[s] for treating bipolar disorder" or any other mental disease or disorder, as implied by the specification (p. 7 of the Response).

The Court in *Brenner v. Manson* held that "[t]he basic *pro quid quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to

this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." See *Brenner* 383 U.S. at 534, 148 USPQ at 695.

In the instant case, characterization of the interaction between KCNQ and PP2A, as the polypeptides being expressed in the brain and regulated by a drug known to treat bipolar disorder, is clearly not sufficient to establish the biological significance of this interaction to bipolar disorder or to any mental disorder in general. Since the instant specification fails to present any evidence or sound scientific reasoning that the KCNQ/PP2A activity/ binding has any specific physiologic effect in etiology or course of a mental disorder, a skilled practitioner would not reasonably believe that administration of a compound "capable of inhibiting phosphorylation of the polypeptide of SEQ ID NO: 2" would have any effect on the course of the disease. In the terms used by the *Brenner* Court, such a characterization does not provide a specific utility in currently available form.

Applicant presents a set of experimental findings and claims KCNQ polypeptides and encoding polynucleotides as useful "for identification compounds suitable for the treatment of diseases" (p. 5) but the specification does not disclose how to interpret those data. Just as the process claimed in *Brenner* lacked utility because the specification did not disclose how to use the end-product, the method claims here lack utility, based on the use of the product, because the specification provides no meaningful guidance on how such information would allow those skilled in the art to use the compounds identified by the claimed method in a specific substantial way.

The Supreme Court in *Brenner* held that the grant of patent rights to an applicant is justified only by disclosure of an invention with substantial utility – a specific benefit in currently available form. Until the invention has been refined and developed to this point, the Court held, the applicant has not met his side of the bargain, and has not provided a disclosure that justifies granting him the right to exclude others. See *id.*

Thus, since the instant specification does not disclose a credible "real world" use for the polypeptide of SEQ ID NO: 2, then the claimed polypeptide as well as encoding polynucleotides do not meet the requirements of 35 U.S.C. § 101 as being useful. The instant rejection is maintained.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 50-52, 54-56, 58-60 and 87 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Double Patenting

8. Applicant is advised that should claim 50 be found allowable, claim 51 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof for reasons of record in section 13 of Paper mailed on May 07, 2007.

Conclusion

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

November 13, 2007